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Hetero Labs Limited, and Hetero USA, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____)	
OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 15-cv-00161-JBS-KMW
)	
HETERO DRUGS LIMITED, HETERO LABS)	
LIMITED and HETERO USA, INC.,)	
)	
Defendants.)	
_____)	

**DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT FOR PATENT
INFRINGEMENT, COUNTERCLAIMS, AND DEMAND FOR JURY TRIAL**

Defendants Hetero Drugs Limited, Hetero Labs Limited, and Hetero USA, Inc.

("Hetero"), by and through its undersigned counsel, hereby respond to the Complaint for Patent Infringement by Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Plaintiff" or "Otsuka") as follows:

THE PARTIES

1. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore, denies those allegations.

2. Admitted.

3. Admitted.

4. Admitted.

NATURE OF THE ACTION

5. Hetero admits that Plaintiff's Complaint purports to be an action for infringement of U.S. Patent No. 8,580,796, U.S. Patent No., 8,642,760, and U.S. Patent No. 8,759,350, arising under the United States patent laws, 35 B.SC. § 100 *et seq.*, including 35 B.SC. §§ 271 and 281, related to Hetero USA, Inc.'s filing of an Abbreviated New Drug Application ("AND") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 B.SC. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell and offer to sell generic pharmaceutical products prior to the expiration of the asserted patents. Hetero denies that Plaintiff has any basis for its claims against Hetero.

JURISDICTION

6. Paragraph 6 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest subject-matter jurisdiction in this case.

7. Paragraph 7 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest personal jurisdiction over Hetero Drugs Limited in this judicial district for the limited purpose of this action. Hetero further states that Hetero's website speaks for itself. Hetero admits that Hetero

Drugs Limited and/or its subsidiary manufactures, imports, markets and sells pharmaceutical drug products, including generic drugs, throughout the United States.

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest personal jurisdiction over Hetero Labs Limited in this judicial district for the limited purpose of this action. Hetero further admits that Hetero Labs Limited and/or its subsidiary manufactures, imports, markets and sells pharmaceutical drug products, including generic drugs, throughout the United States, and that it is the Drug Master File holder for the aripiprazole active pharmaceutical ingredient used in its generic aripiprazole products. Hetero further admits that Hetero Labs Limited has previously submitted to this Court's jurisdiction by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest personal jurisdiction over Hetero USA, Inc. in this judicial district for the limited purpose of this action. Hetero further admits that Hetero USA, Inc. imports, markets and sells active pharmaceutical ingredients throughout the United States. Hetero denies that Hetero USA imports, markets and sells dosage form products throughout the United States. Hetero denies that Hetero USA, Inc. manufactures pharmaceutical drug products, including generic drugs, throughout the United States. Hetero admits that Hetero USA, Inc. is registered to do business in New Jersey under Business I.D. No. 0400362826 and that it is registered as a Wholesaler in the State of New Jersey (No. 5004050) under the trade name "Hetero USA, Inc." Hetero further admits that Hetero USA, Inc. has previously submitted to this Court's jurisdiction by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Hetero admits that Hetero Drugs Limited, Hetero Labs Limited, and Hetero USA, Inc. operate as a single integrated business. Hetero admits that Hetero Drugs Limited and Hetero Labs Limited share common corporate directors. Hetero states that Hetero's website speaks for itself.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest that venue is proper in this district for the limited purpose of this action.

FIRST COUNT FOR PATENT INFRINGEMENT

12. Hetero admits that a document purporting to be a copy of U.S. Patent No. 8,580,796 (the "'796 Patent'") entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof," and stating on its face that it issued on November 12, 2013, is attached as Exhibit A to the Complaint.

13. Hetero admits that Otsuka Pharmaceutical Co., Ltd. is listed on the face of Exhibit A as the purported assignee of the '796 Patent.

14. Hetero admits that the electronic version of the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (the "*Orange Book*") lists the patent expiration date for the '796 Patent as September 25, 2022, with a period of pediatric exclusivity expiring on March 25, 2023. Hetero denies all other allegations in paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero denies the allegations in paragraph 15 of the Complaint.

16. Hetero admits that the FDA's website lists Otsuka Pharmaceutical Co., Ltd. as the applicant for NDA No. 21-436 for aripiprazole tablets and that the FDA's approval date is listed as November 15, 2002. Hetero denies all other allegations in paragraph 16 of the Complaint.

17. Hetero admits that the '796 Patent is included in the *Orange Book* list of Patent Data associated with NDA No. 21-436.

18. Hetero admits that the *Orange Book* lists the Proprietary Name of aripiprazole tablets as Abilify. Hetero is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 of the Complaint and, therefore, denies those allegations.

19. Admitted.

20. Admitted.

21. Admitted.

22. Hetero denies that Hetero's generic products will, if approved and marketed, infringe at least one claim of the '796 Patent.

23. Hetero denies that it has infringed at least one claim of the '796 Patent by submitting, or causing to be submitted, ANDA No. 205064 to the FDA seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '796 patent.

24. Hetero denies that it has cooperated with, participated in, assisted, induced, or benefitted from, any infringement of the '796 Patent through its submission of ANDA No. 205064.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Hetero incorporates and reiterates the above responses to the allegations set forth in paragraphs 1-24 of the Complaint as if fully set forth herein.

26. Hetero admits that a document purporting to be a copy of U.S. Patent No. 8,642,760 (the “’760 Patent”) entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof,” and stating on its face that it was issued on February 4, 2014, is attached as Exhibit B to the Complaint.

27. Hetero admits that Otsuka Pharmaceutical Co., Ltd. is listed on the face of Exhibit B as the purported assignee of the ’760 Patent.

28. Hetero admits that the electronic version of the *Orange Book* lists the patent expiration date for the ’760 Patent as September 25, 2022, with a period of pediatric exclusivity expiring on March 25, 2023. Hetero denies all other allegations in paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero denies the allegations in paragraph 29 of the Complaint.

30. Hetero admits that the ’760 Patent is included in the *Orange Book* list of Patent Data associated with NDA No. 21-436.

31. Admitted.

32. Admitted.

33. Hetero denies that Hetero’s generic products will, if approved and marketed, infringe at least one claim of the ’760 Patent.

34. Hetero denies that it has infringed at least one claim of the '760 Patent by submitting, or causing to be submitted, ANDA No. 205064 to the FDA seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '760 patent.

35. Hetero denies that it has cooperated with, participated in, assisted, induced, or benefitted from, any infringement of the '760 Patent through its submission of ANDA No. 205064.

THIRD COUNT FOR PATENT INFRINGEMENT

36. Hetero incorporates and reiterates the above responses to the allegations set forth in paragraph 1-35 of the Complaint as if fully set forth herein.

37. Hetero admits that a document purporting to be a copy of U.S. Patent No. 8,759,350 (the "'350 Patent") entitled "Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders," and stating on its face that it issued on June 24, 2014, is attached as Exhibit C to the Complaint.

38. Hetero admits that Otsuka Pharmaceutical Co., Ltd. is listed on the face of Exhibit C as the purported assignee of the '350 Patent.

39. Hetero admits that the electronic version of the *Orange Book* lists the expiration date of the '350 Patent as March 2, 2027. Hetero denies all other allegations in paragraph 39 of the Complaint.

40. Paragraph 40 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero denies the allegations in paragraph 40 of the Complaint.

41. Hetero admits that the '350 Patent is included in the *Orange Book* list of Patent Data associated with NDA No. 21-436.

42. Admitted.

43. Admitted.

44. Hetero denies that Hetero's generic products will, if approved and marketed, infringe at least one claim of the '350 Patent.

45. Hetero denies that it has infringed at least one claim of the '350 Patent by submitting, or causing to be submitted, ANDA No. 205064 to the FDA seeking approval to manufacture, use, offer to sell and sell Hetero's generic products before the expiration date of the '350 patent.

46. Hetero denies that it has cooperated with, participated in, assisted, induced, or benefitted from, any infringement of the '350 Patent through its submission of ANDA No. 205064.

ANSWER TO PRAYER FOR RELIEF

Defendant denies that Plaintiff is entitled to the judgment and relief Plaintiff requests in the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiff's § 271(a)-(c) infringement claim fails to state a claim under Rule 12(b)(6). Plaintiff bases its § 271(a)-(c) claim against Hetero on alleged possible future acts of infringement by Hetero if the FDA approves Hetero's ANDA in the same form as currently filed. Such highly speculative acts of alleged future infringement cannot support a claim of direct and

indirect infringement under § 271(a)-(c). Plaintiff has not alleged any past or present infringement in the Complaint to support its § 271(a)-(c) claims of infringement.

Second Affirmative Defense

Hetero does not infringe and has not infringed any valid and enforceable claim of the '796 Patent, the '760 Patent, or the '350 Patent, and will neither induce nor contribute to the infringement of any valid and/or enforceable claim of the '796 Patent, the '760 Patent, or the '350 Patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense

Each and every claim of '796 Patent, the '760 Patent, and the '350 Patent is invalid because they fail to satisfy one or more conditions for patentability stated in Title 35 of the United States Code, including, *inter alia*, §§ 101, 102, 103 and 112.

Fourth Affirmative Defense

Plaintiff's claims for relief are barred, in whole or in part, by the doctrine of prosecution history estoppel.

Fifth Affirmative Defense

Plaintiff's claims for relief are barred, in whole or in part, by one or more of the equitable doctrines of laches, waiver, estoppel and/or unclean hands.

Sixth Affirmative Defense

Plaintiff's claims for injunctive relief are barred because Plaintiff has an adequate remedy at law, has not been irreparably harmed, the balance of hardships is not in its favor, and the public interest is not served by granting injunctive relief.

Seventh Affirmative Defense

Plaintiff's claims for damages are limited and/or barred under 35 U.S.C. §§ 286 and 287.

Eighth Affirmative Defense

Hetero expressly reserves the right to amend this Answer to assert additional defenses, cross-claims, and/or other claims and defenses that may become known to it through discovery, including, but not limited to, inequitable conduct.

COUNTERCLAIMS

Hetero, for its Counterclaims against Otsuka, alleges as follows:

1. Hetero Drugs Limited is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018 A.P., India.
2. Hetero Labs Limited is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018 A.P., India.
3. Hetero USA, Inc. is a Delaware corporation having its principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey 08854.
4. Upon information and belief, Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201, 2202, under the United States patent laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).
6. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1118(a), 2201, and 2202, and 21 U.S.C. § 355(j)(5)(C)(i)(ii).

7. Personal jurisdiction over Counterclaim-Defendant exists because Counterclaim-Defendant has submitted to the personal jurisdiction of this Court.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(ii).

BACKGROUND

9. Upon information and belief, the United States Patent and Trademark Office issued U.S. Patent No. 8,580,796 (the “’796 Patent”) on November 12, 2013, listing Otsuka as the assignee.

10. Upon information and belief, the United States Patent and Trademark Office issued U.S. Patent No. 8,642,760 (the “’760 Patent”) on February 4, 2014, listing Otsuka as the assignee.

11. Upon information and belief, the United States Patent and Trademark Office issued U.S. Patent No. 8,759,350 (the “’350 Patent”) on June 24, 2014, listing Otsuka as the assignee.

12. Counterclaim-Defendant Otsuka filed the Complaint in this district on January 8, 2015, claiming infringement of the ’796 Patent, the ’760 Patent, and the ’350 Patent, and alleging that Hetero has infringed on the ’796 Patent, the ’760 Patent, and the ’350 Patent.

13. Hetero denies infringement of the ’796 Patent, the ’760 Patent, and the ’350 Patent and alleges that the ’796 Patent, the ’760 Patent, and the ’350 Patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Laws, including 35 U.S.C. §§ 101, *et seq.*

14. Therefore, there is an actual and justiciable case or controversy between Hetero and Otsuka regarding the alleged infringement and validity of the '796 Patent, the '760 Patent, and the '350 Patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '796 Patent)

15. Hetero re-alleges and incorporates each of the preceding paragraphs 1-14 as if fully stated herein.

16. Hetero has not infringed, does not infringe, will not infringe, and will not contribute to or induce the infringement of any valid and/or enforceable claim of the '796 Patent, either literally or under the doctrine of equivalents.

17. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that Hetero has not and will not infringe the claims of the '796 Patent.

COUNT II
(Declaratory Judgment of Invalidity of the '796 Patent)

18. Hetero re-alleges and incorporates each of the preceding paragraphs 1-17 as if fully stated herein.

19. Each claim of the '796 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

20. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that each of the claims of the '796 Patent is invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '760 Patent)

21. Hetero re-alleges and incorporates each of the preceding paragraphs 1-20 as if fully stated herein.

22. Hetero has not infringed, does not infringe, will not infringe, and will not contribute to or induce the infringement of any valid and/or enforceable claim of the '760 Patent, either literally or under the doctrine of equivalents.

23. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that Hetero has not and will not infringe the claims of the '760 Patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '760 Patent)

24. Hetero re-alleges and incorporates each of the preceding paragraphs 1-23 as if fully stated herein.

25. Each claim of the '760 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

26. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that each of the claims of the '760 Patent is invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '350 Patent)

27. Hetero re-alleges and incorporates each of the preceding paragraphs 1-26 as if fully stated herein.

28. Hetero has not infringed, does not infringe, will not infringe, and will not contribute to or induce the infringement of any valid and/or enforceable claim of the '350 Patent, either literally or under the doctrine of equivalents.

29. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that Hetero has not and will not infringe the claims of the '350 Patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '350 Patent)

30. Hetero re-alleges and incorporates each of the preceding paragraphs 1-29 as if fully stated herein.

31. Each claim of the '350 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

32. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that each of the claims of the '350 Patent is invalid.

REQUEST FOR RELIEF

1. WHEREFORE, Hetero respectfully requests that this Court enter a Judgment and Order in its favor and against Counterclaim-Defendant as follows:

- A. Dismissing Counterclaim-Defendant's Complaint and rendering Judgment in favor of Hetero;
- B. Declaring that Hetero does not and will not infringe any valid and/or enforceable claim of the '796 Patent;
- C. Declaring that the claims of the '796 Patent are invalid;

- D. Declaring that Hetero does not and will not infringe any valid and/or enforceable claim of the '760 Patent;
- E. Declaring that the claims of the '760 Patent are invalid;
- F. Declaring that Hetero does not and will not infringe any valid and/or enforceable claim of the '350 Patent;
- G. Declaring that the claims of the '350 Patent are invalid;
- H. Declaring that this is an exceptional case under 35 U.S.C. § 285 and/or other applicable laws and awarding Hetero its attorneys' fees, costs and expenses in this action; and
- I. Awarding to Hetero such further relief as this Court may deem necessary, just, and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Hetero demands a trial by jury.

Date: March 16, 2015

HETERO DRUGS LIMITED, HETERO LABS
LIMITED AND HETERO USA, INC.,

By its attorneys,

/s/ David Leit

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